



2020-21 Pre-Budget Submission

Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognise their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfil their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens - support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Overview:

Johnson & Johnson (J&J) is committed to improving lives through better health outcomes whether that's through cutting edge medicines and medical technologies or products Australians trust for their health, beauty and baby care.

Because of our global reach and experience, we have a unique perspective on the health and wellness needs, wants, hopes and fears of the people who invite us into their lives and their homes.

We are in a powerful position to help transform global healthcare; shine a light on the most important health and wellness issues we face; collaborate across boundaries and borders; uncover scientific insights and ideas; and dedicate resources towards creating tomorrow's breakthroughs.

We have a long-standing commitment to fight established and emerging epidemics and stand ready to support global efforts where it may make a difference. We are a world leader in developing treatments and vaccines for infectious diseases and for our pandemic response. We work across the globe to eradicate HIV, tuberculosis, malaria, Ebola, Zika and other diseases as they arise.

A powerful example is our approach to HIV. In July J&J commenced the Mosaic Study, a Phase-3 trial of a vaccine designed to protect against a wide range of HIV-1 strains that are responsible for the global epidemic. The trials have a target enrollment of 3800 individuals across North America, South America and Europe targeting women, homosexual men and transgender people.

A timely example for Australia and our region is our immediate commitment to working on a vaccine for coronavirus. We are mobilizing all available resources in response to this most recent crisis. Two weeks ago, when the sequence of the virus became available, we immediately got together with the team to assess whether we can leverage current platforms to develop a vaccine. Based on our experience with other viral vaccines, we are cautiously optimistic that it's feasible. We have mobilised internal resources and our external partners to bring the power and reach of our global network to address this crisis.

J&J is comprised of a leading pharmaceutical business – Janssen; a medical technology business – Johnson & Johnson Medical – and our consumer health business – Johnson & Johnson Pacific.

We work constructively and transparently with Government across our businesses to ensure timely and cost-effective consumer, patient and clinician access to our products. We appreciate the opportunity to inform the Government's 2020/21 Budget considerations.

J&J makes a significant economic and social contribution to Australia, notwithstanding our foreign ownership. Our annual investment in Australia is almost \$2 billion. That investment creates a total economic impact of \$4.4 billion per annum in Australia.¹

We employ more than 1,440 workers across the country with diverse roles in research and development, manufacturing, operations, sales, marketing and supply chain. In addition to these direct jobs, we have created almost 5,820 additional jobs through our supply chain and partnerships.

J&J has conducted more than 71 clinical trials, at 365 sites across Australia with the support of more than 1,460 patients. Our trials have focused on advancing the treatment of cancer, diabetes, HIV,

¹ Johnson & Johnson, *Economic & Social Footprint Study Australia*, March 2019.

atrial fibrillation, degenerative spinal disease, schizophrenia, hernia, hip necrosis, multiple myeloma and ulcerative colitis.

Ensuring access to life-saving medical treatments and technologies:

J&J supports the Australian Government's commitment to delivering new and emerging therapies and treatments to Australian patients. Australia has a world class health system of which we can all be proud, however the Government must ensure that the regulatory, health technology assessment and reimbursement frameworks keep pace with technology and the global innovation landscape.

J&J commends the Government's commitment to list all positive PBAC recommendations which recognises the importance of timely access to new treatments for Australian patients. We appreciate the significant amount of money required to meet this commitment and we work constructively with Government to ensure cost effective access to our life saving treatments.

Despite successive Governments committing to listing new and innovative medicines, the amount invested in the PBS per annum has remained flat for nearly a decade while the cost of bringing new treatments to patients continues to rise. This imbalance is increasingly impacting Australian patient's ability to access life-saving medicines.

J&J supports the pre-Budget submission made by Medicines Australia which recommends increased and sustained investment in the PBS. The global landscape for pharmaceuticals has also changed and Australia's standing as a leading economy for investment in medicines has fallen. Increased investment in the PBS would go some way towards ensuring Australia's investment is at the level of other comparable countries.

J&J also supports Medicines Australia's call for the requirement for the Department of Health to find offsets from within the portfolio to fund medicine reimbursement to be abandoned. These constraints make it difficult to bring new and innovative treatments to Australia.

A sustainable Private Healthcare sector:

Globally, J&J supports the expansion of public and private financing of healthcare that expands access to life-saving treatments, therapies and technologies for patients everywhere. We support reforms designed to improve timely patient access to innovative products and services and which foster sustainable levels of investment in healthcare.

Australia's private health system complements the public system by providing more tailored care options, broader clinician choice and reduced waiting times. It reduces pressure on finite taxpayer resources devoted to public health. Private health insurance is an essential part of the Australian healthcare landscape and it is in everyone's interests to ensure that health insurance products remain accessible, affordable and attractive to Australian consumers.

J&J is committed to improving the value proposition of private health insurance to increase the PHI participation rate which is currently at an 11-year low of 44.1 per cent. We note the recent private health insurance premium round has delivered an average premium increase of 2.92 per cent – the lowest in almost two decades.

The medical technology industry in Australia has substantially contributed to keeping premiums low through of medical device price cuts delivered in 2018 and a further tranche of price cuts to come into effect in early 2020 totaling \$1.1 billion. These price reductions were the basis of a Strategic Agreement signed between the Commonwealth and the Medical Technology Association of Australia (MTAA) which is in place until 2022. This agreement provides stability and certainty to the

healthcare industry – including patients, surgeons and hospitals planning life-saving and life-enhancing surgeries.

Australians seek value for money in the significant investments they make on behalf of themselves and their families, including their investment in private health insurance. Australia's long history of supporting the private health insurance industry through Government subsidy and other incentives, means Australians deserve to demand value for themselves as policyholders, as well as taxpayers.

The 'value' in private health insurance products will differ for each individual, reflecting their personal circumstances, and it will often change over time. That value is linked to the benefits on offer in the private system that differ from the public system such as choice of hospital and surgeon; the timing and location for a procedure; and access to the best treatments and technologies available.

J&J is concerned that commentary around cost drivers in healthcare, driven by the very profitable private health insurance industry, is eroding value in private healthcare and contributing to driving people away from private health insurance. By diminishing access to the very services that consumers value, the attractiveness of private health insurance is also diminished. Why would consumers pay extra to receive care of the standard a patient would receive in the public healthcare system?

J&J supports a comprehensive review of private health insurance with a view to reforming the landscape to ensure the sustainability of private healthcare and to arrest the decline in membership.

We note reforms introduced by the Government to improve transparency, affordability and comparability of insurance products; and measures taken to engage with industries and parties that are an essential part of the private health insurance eco-system (such as specialists, private hospitals and medical device companies) to deliver savings and efficiencies that are helping to contain private health insurance premium growth to historically low levels.

We note the Government has committed to a further wave of reforms to private health insurance. J&J looks forward to participating in a public consultation process around those reforms where they impact on the access and affordability of medical technology and medicines and the broader private healthcare landscape.

As part of these reforms, we ask the Government to consider recommendations contained in the Alpha Beta report commissioned by the MTAA "Keeping Premiums Low: Towards a sustainable private healthcare system". This report outlines a range of collaborative sector-wide measures that can be taken to ensure the ongoing sustainability of our private healthcare system.

This report proposes a sensible path to reform, with a range of short and longer-term savings and structural solutions and we encourage further consideration of its recommendations by Government.

Greater emphasis on self-care and preventative health

J&J supports the pre-Budget submission made by Consumer Healthcare Products (CHP) Australia.

The submission advocates for self-care to be embedded in national health policy, as a contributor to preventing illness, improving health outcomes, and fostering a more cost-effective health care system.

Self-care involves individuals taking greater personal interest in, and responsibility for, their own health and well-being through better lifestyle choices and risk avoidance, responsible use of medicines, diet and exercise.

Increased consumer empowerment, access to medicines and improved health literacy are key aspects to enabling greater self-care through over the counter medicines, smoking cessation aids, sunscreens and skincare.

Responsible self-care is the first step individuals should take to managing their wellbeing, live healthy, prevent and limit illness, and use healthcare services efficiently.

We support the Government's strong stance on reducing the smoking rates in Australia. J&J is a leader in nicotine replacement therapies and will work with the Federal and State Governments, their agencies and the broader healthcare industry to promote the benefits of smoking cessation.

Development of a National Obesity Strategy

In October 2018, the Council of Australian Governments (COAG) Health Council agreed that a national obesity strategy be developed to guide government action over the next 10 years to reduce overweight and obesity in Australia.

The National Obesity Strategy Working Group has sought public feedback which will be used to shape a strategy that the COAG Health Council will consider for approval in late 2020. The objective of the strategy is to provide a framework for partners, including the non-government and private sector, communities and individuals, to take collaborative action to address obesity through a shared agenda.

J&J commends COAG for this undertaking and has made a submission. The proposed scope of the strategy currently excludes medical interventions and treatment that have been proven to prevent obesity related disease. J&J is of the view the strategy must expand its scope to include treatment to ensure the strategy delivers on its stated vision and principles.

People living in areas of most disadvantage are 10 per cent more likely to be affected by obesity than those living in areas of least disadvantage, and obesity contributes to about 15 per cent of the health gap between Aboriginal and Torres Strait Islander people and non-indigenous people. Equal access to the most effective treatments must be examined and addressed over the coming years to ensure they are accessible to all Australians, regardless of age, living location, cultural background and income.

J&J agrees and supports the strategy's focus on addressing long-term behaviour change including improvements to diet and increased physical activity. However, the strategy must not neglect the significant number of Australians, estimated to be more than 9 per cent of the adult population (AIHW), who are living with severe obesity now, and who are less likely to respond to the primary and secondary preventive measures proposed in the strategy consultation paper.

Mental health and suicide prevention

J&J has a long history in the treatment of mental health. For decades we have invested in research and innovation which has created better outcomes for people living with mental health conditions.

While we have a heritage in treatments for schizophrenia, we are investing in R&D around the world, as well as locally, to find new treatments for neurodegenerative diseases and mood disorders.

We continue to raise awareness and eliminate stigma both with our employees and in partnership with mental health organisations in Australia and overall, we aim to create a world where those in need have access to care and never have to suffer silently.

We support and applaud the Government's commitment to addressing Australia's mental health challenges and helping to reduce the suicide rate in Australia and will continue to work with Government and the sector to advance the Government's commitments.

Health security in the Pacific:

J&J congratulates the Australian Government for committing \$242 million to the Sixth Global Fund to fight AIDS, Tuberculosis and Malaria. J&J has a strong relationship with the Global Fund and has been supporting global efforts to end TB and Antimicrobial Resistance for nearly 20 years.

J&J supports the Government's recent announcement regarding the \$13 million commitment to support global efforts to control and eliminate TB in the South East Asia and Pacific Region and will work with the Department of Foreign Affairs and Trade and the Department of Health once submissions open.

In September 2018, J&J reaffirmed its commitment to the fight against TB by announcing a 10-year initiative to expand access to treatments by offering a not-for-profit price to 130+ low and middle income countries as well as non-governmental organisations.

Changes to the Research & Development Tax Credit:

J&J echoes the health and life-sciences industry's disappointment in the Government's decision to change the R&D tax incentive despite widespread opposition and the recommendation of a Senate Committee to defer the Bill until further consideration was given to the effect of the reforms.

The Senate Committee recognised that further changes to the R&D tax incentive creates business uncertainty especially when incentives are proposed to be weakened, not strengthened. The proposed changes have the potential to significantly impact on industry's ability to innovate, invest and deliver new treatments to Australian patients.

It is troubling that the Bill contains the introduction of an intensity threshold for the research intensive pharmaceutical sector, which would diminish Australia's attractiveness as a destination for clinical research at a time when we are seeking to expand Australia's export capacity in the knowledge economy that includes clinical research expertise and infrastructure.

J&J supports AusBiotech's position in relation to the proposed changes outlined below and calls on the Government to reconsider its position.

- Fixing the rate of the refundable R&D tax offset to 13.5%
This change will immediately hit biotech SMEs with a 2.5 percent loss of refund if passed – a move both significant and material: for each \$1 million of expenditure, the loss will be \$25,000 that has to be raised by alternate means.
- A simplified R&D Premium for conducting 'high intensity' R&D for companies with an annual turnover of more than \$20 million

Despite being simplified from the last Bill, the intensity measure still reduces the support for all but a few companies. It will prove hard to estimate in advance, which undermines the certainty that most companies have traditionally had in relation to future RDTI calculations.

- An increase in the R&D expenditure threshold rate from \$100 million to \$150 million
While this is welcome, it is only applicable to a few companies, with the potential addition of one or two more in years to come.
- Claim gap set at \$4 million, with an exemption for clinical trials
While the protection of clinical trials is welcome, it has been tempered by the high degree of confusion that remains about the definition of “clinical trial” and which expenditure would be eligible for the RDTI under the proposed changes.

Strengthening Intellectual Property:

Australia is a competitor for global investment and needs to ensure that its intellectual property regime is globally competitive. There are a number of aspects that could be more competitive such as data package exclusivity (a right unique to medicines that better supports research and development of new uses for existing molecules) and patent linkage (notification of an application to register a generic medicine that improves the opportunity to avoid unnecessary patent litigation).

J&J remains concerned about the Australian Government’s policy of seeking monetary damages from an innovator company in cases where a patent claim in Australia, which is the subject of interlocutory relief, is held invalid by the courts.

The Government has sued companies for damages attributed to a delay in the PBS price reduction while the patent dispute is being resolved. These “market-sized damages” create significant uncertainty for pharmaceutical patent owners, that need to be able to rely on the rights conferred by granted patents (unless and until they are finally invalidated) to support the large investments needed to develop new medicines. It also undermines the rights of patent holders in Australia by introducing a strong disincentive to exercise their core right to enforce their intellectual property protections.

The uncertainty is exacerbated by the difficulty in resolving patent challenges prior to competitor market entry, due to lack of adequate patent holder notification. Australia has not implemented a system by which patent holders, as a matter of practice, receive advance notice of third-party applications for marketing approval of potentially patent-infringing pharmaceutical products.

In the rare circumstances where advance notice is provided, the amount of notice is inadequate to enable the final resolution of any patent infringement claims before the relevant third-party product obtains regulatory approval for market entry during the term of the relevant patent/s.

J&J has welcomed the TGA consultation looking at whether the TGA should publish that a prescription medicine is under evaluation. This consultation has proposed an option that the TGA would provide public notice when generic and biosimilar medicines apply for evaluation prior to acceptance on the Australian Register of Therapeutic Goods (ARTG). If the Minister for Health accepts this as a recommendation from the TGA, the effect will be to afford approximately 12 months’ notice of a generic/biosimilars intent to enter the market.

